

K964353

**SUMMARY OF SAFETY AND EFFECTIVENESS**

**NIDEK CyberLase CO2 LASER SYSTEMS**

**FEB 28 1997**

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**REGULATORY AUTHORITY:**

Safe Medical Devices Act of 1990, 21CFR 807.92

**COMPANY NAME/CONTACT:**

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**DEVICE TRADE NAME:**

CyberLase CO2 Laser System

**DEVICE COMMON NAME:**

CO2 Surgical Laser System

**DEVICE CLASSIFICATION:**

CO2 laser system have been classified as Class II (79GEX) medical devices by the OB/GYN, General, Plastic Surgery and ENT Device Advisory Panels. To the best of our knowledge, CO2 laser delivery system has not been classified.

**PERFORMANCE STANDARDS:**

The laser systems manufactured by Nidek Inc. comply with 21 CFR 1040.10 and 1040.11, FDA regulations for medical laser products, as applicable Nidek Inc. is unaware of any specific standards for CO2 laser delivery systems.

#### INDICATIONS FOR USE STATEMENT:

The CyberLase CO2 Laser Systems are intended for the surgical removal (i.e., excision, incision, cutting, ablation, coagulation, homeostasis or vaporization) of soft tissue in all surgical applications with the use of wavelength of 10.6µm. Areas to be covered are:

Head and Neck(ENT) including Uvulopalatoplasty, Neurosurgery, General / Plastic Surgery, Dermatology, Oncology, Obstetrics/Gynecology, Orthopedics, Polymethylmethacrylate(PMMA) Removal during Revision Arthroplasty Procedures, and Thoracoscopic applications.

#### COMPARISON WITH PREDICATE DEVICE:

The Nidek CO2 Laser system is substantially equivalent to the Heraeus LaserSonics Paragon Laser System.

The risks and benefits of the Nidek CyberLase CO2 Laser System is comparable to the predicate device when used for similar clinical applications.

Since the Nidek CyberLase CO2 Laser System is substantially equivalent with respect to indications for use, materials, method of operation and physical construction to the predicate device, we believe it clearly meets the requirement for substantial equivalence according to Section 510(k) guidelines. Safety and effectiveness are reasonably assured, therefore justifying 510(k) clearance for commercial sale.